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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,476	09/25/2000	Jose Ramon Botella	3573-110.1-US	2564

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EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/669,476

Applicant(s)

BOTELLA, JOSE RAMON

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The rejection of Claims 54-57 and 59 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendments.
2. The substitute specification filed 10/1/02 has been entered.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 34-46 have been cancelled.

Claim Rejections - 35 USC § 112

5. Claims 34-46 are cancelled. Claims 47-59 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/26/02. Applicants arguments filed January 7, 2003 have been considered but are not deemed persuasive.

Applicant asserts that the claim of a nucleotide sequence "of sufficient length to regulate the level of ACC synthase gene expression" does not make any additional requirements for identifying only those sequences that selectively and completely inhibit ACC synthase genes. (response page 4); and that the variability in silencing a gene with one length of sequence compared to another is not unpredictable to the extent that undue experimentation is required to employ the Applicant's structurally and functionally defined sequences (response page 5). Given the examples of unpredictability cited in the enablement rejection with respect to antisense

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fragments it is clear that there is no reasonable correlation between the unspecified and unexemplified "nucleotide sequences of sufficient length" of the claims and the level of the art.

Applicant asserts that the state of the art as indicated by Bourque *et al.* and by the Applicant in the disclosure, the use of the sequences as structurally and functionally defined by Applicant to regulate ACC synthase is, and was at the time of the invention a predictable area (response page 5). It is important to note that both Bourque *et al.* and Applicant do not describe either structurally or functionally any sequences other than full length. Nowhere is there any guidance whatsoever for making and using sequences of sufficient length.

Further, Applicant asserts that the Examiner has identified examples in the prior art of variability in terms of the level of efficacy of certain gene fragments in antisense expression (response page 5). Let it be made clear for the record, the examples cited in the references show both an instance whereby gene expression was unaffected by a 5' half of the CHS gene expressed antisense in petunia and another instance of the CHS gene expressed antisense whereby the transformant exhibited an increase in gene expression.

Applicant asserts that the instant claims 47-59 now encompass subject matter that can be practiced by a person of ordinary skill in the art, using the disclosure provided, without recourse to undue experimentation (response page 5). Given the lack of guidance and the lack of working examples in the specification, the breadth of the claims, with respect to the use of the phrase "of sufficient length to regulate ACC synthase gene expression", and the unpredictability in the art, undue trial and error would be needed to practice the invention as claimed. Therefore the invention is not enabled commensurate with the scope of the claims.

Furthermore, as noted in the prior office action, Applicant has not provided guidance for production of transgenic papaya or mango with inhibited fruit senescence. Applicant has not responded to this aspect of the rejection.

Double Patenting

6. Claims 34-46 are cancelled. Claims 47-59 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,124,525. This rejection is maintained for the reasons of record set forth in the Official actions mailed 23/26/02. Applicants arguments filed 1/07/2003 have been considered but are not deemed persuasive.

Applicant asserts that Applicant will submit a terminal disclaimer upon indication of allowable subject matter (response, page 7). However, a statement of intent does not overcome the rejection, and therefore the rejection is maintained.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.